K091219

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

General Company Information

OCT - 2 2009

Name:	Musculoskeletal Transplant Foundation
Contact:	Nancy Bennewitz Joy Regulatory Affairs Submission Specialist
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Date Prepared

August 5, 2009

General Device Information

Product Name:	DBX® Inject
Classification:	Bone Void Filler Containing Human Demineralized Bone Matrix (DBM) 21 CFR §872.3930 – Product code: NUN Class II

Predicate Devices

DBX® Demineralized Bone Matrix
Musculoskeletal Transplant Foundation
510(k) K040262

Sygnal™ DBM
Musculoskeletal Transplant Foundation
510(k) K080405

Osteoinductive Potential:

DBX® Inject is osteoconductive, and has been shown to have osteoinductive potential in an athymic mouse model. Every lot of final DBX® Inject Paste will be assayed *in vivo* for osteoinductive potential. Every lot of final DBX® Inject Putty product will be tested in an athymic mouse model or in an alkaline phosphatase assay, which has been shown to have a positive correlation with the athymic mouse model, to ensure the osteoinductive potential of the final product. Standard testing performed in an athymic mouse or alkaline phosphatase assay must prove positive for lot release. It is unknown how the osteoinductive potential, measured in the athymic mouse model or the alkaline phosphatase assay, will correlate with clinical performance in human subjects.

Viral Clearance and Inactivation:

The method for processing the demineralized bone matrix contained in DBX® Inject was evaluated for its viral inactivation potential. A panel of model potential human viruses representing various virus types, sizes, shapes and genomes were evaluated. The DBM processing methods were determined to provide significant viral inactivation potential for a wide range of potential viruses.

Safety and Effectiveness Information

DBX® Inject is single-donor processed. The donor suitability criteria used to screen this donor are in compliance with the FDA regulations published in 21 CFR Part 1270 and Part 1271 Human Tissue Intended for Transplantation.

Conclusion

Musculoskeletal Transplant Foundation believes that the information provided in this 510(k) submission establishes that similar legally marketed devices have been used for the same clinical applications as the DBX® Inject. The materials from which DBX® Inject is fabricated have an established history of use, and the device has been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

Ms. Nancy Bennewitz Joy
Regulatory Affairs Submission Specialist
Musculoskeletal Transplant Foundation
125 May Street
Edison, New Jersey 08837

OCT – 2 2009

Re: K091217
Trade/Device Name: DBX® Inject
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NUN
Dated: September 29, 2009
Received: September 29, 2009

Dear Ms. Joy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K091217

Device Name: DBX® Inject

Indications for Use:

DBX® Inject is intended for use as a Demineralized Bone Matrix for voids or gaps that are not intrinsic to the stability of the bony structure. It can be used as follows:

Indications for Use	Putty	Paste
Ridge augmentation	√	√
Filling of extraction sites	√	√
Craniofacial augmentation	√	√
Mandibular reconstruction	√	√
Repair of traumatic defects of the alveolar ridge, excluding maxillary and mandibular fracture	√	√
Filling resection defects in benign tumors, benign cysts, or other osseous defects in the alveolar ridge wall	√	√
Filling of cystic defect	√	√
Filling of lesions of periodontal origin	√	√
Filling of defects of endodontic origin	√	√

DBX® Inject is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury. DBX® Inject can be used with bone marrow. DBX® Inject is for single patient use only.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Kevin Mulley for KCR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091217